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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/689,366

10/12/2000

Mike Rothe

T95-005-2

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02/23/2004

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/689,366

Applicant(s)

ROTHE ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 22 is/are allowed.
- 6) ☒ Claim(s) 17 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

Receipt is acknowledged of a Notice of Appeal filed 12/12/2003 and an Appeal Brief filed 12/15/2003. The arguments in the Appeal Brief have been fully considered. Prosecution of this application is hereby reopened. As new grounds of rejection are made herein, this action is not final.

***Response to Arguments***

Applicant's arguments, see the Appeal Brief filed 12/15/2003, with respect to a lack of sufficient written description to describe the broadly claimed genus of proteins encompassed by claims 17 and 18 have been fully considered and are persuasive. The grounds of rejection based on a lack of description for the broadly claimed genus of proteins comprising the BIR domain corresponding to SEQ ID NO: 9 (claim 17) or of the genus of hybrid proteins of claim 18 have been withdrawn. It is noted, however, that the grounds for rejection of claim 17 for incorporating impermissible NEW MATTER do not appear to have been addressed in the Appeal Brief. Therefore, these grounds of rejection are maintained and repeated below.

It is further noted that, upon review of the prosecution history, a new grounds of rejection is made herein against claim 18 (see the Korneluk et al rejection made below). This rejection was originally made against claim 12 in the action mailed 1/15/2002. The rejection is reinstated here because claim 18 does not recite that the hybrid protein necessarily comprises amino acids 287-334 of SEQ ID NO: 2 (i.e. SEQ ID NO: 9). This specific limitation was incorporated into claim 12 in the amendment filed 2/19/2002 and

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obviated the art rejection over Korneluk et al (U.S. Patent No. 5,919,912). Korneluk et al do not teach SEQ ID NO: 9.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record and repeated below.**

Claim 17 is directed to isolated proteins comprising the 3<sup>rd</sup> BIR domain of c-IAP1 (i.e. residues 287-334 of SEQ ID NO: 2 or SEQ ID NO: 9). Claims 17 now comprises additional functional language that specifies that the BIR domain described by SEQ ID NO: 9 provides a protein:protein interaction domain which binds at least one of a specific pair of human tumor necrosis factor proteins (i.e. TRAF1 or TRAF2). There is no literal support in the specification for the functional limitation that the 3<sup>rd</sup> BIR domain of c-IAP1 alone provides a protein:protein interaction with TRAF1 or TRAF2. Nor is there any support anywhere in the specification for the concept that a protein comprising a single BIR domain obtained from c-IAP1 or c-IAP2 necessarily binds TRAF1 or TRAF2. Therefore, these newly added functional limitations are impermissible NEW MATTER.

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It would be remedial to amend the claim language by deleting the phrase “wherein the BIR motif provides a protein:protein interaction domain”.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 18 is drawn to an isolated protein comprising at least two of the following three domains: a first domain comprising SEQ ID NO: 5 or 6, a second domain comprising SEQ ID NO: 7 or 8, and a third domain comprising SEQ ID NO: 9 or 10, wherein the protein binds at least one of a human tumor necrosis factor receptor associated protein 1 (TRAF1) and a human tumor necrosis factor receptor associated protein 2 (TRAF2).

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Korneluk et al (U.S. Patent No. 5,919,912; see the entire document). **This is a new rejection.**

The ‘912 patent teaches the isolation of nucleic acid sequences encoding mammalian IAP polypeptides, methods of producing IAP polypeptides from such sequences, methods of using such nucleic acids and polypeptides to inhibit apoptosis in cells, and methods for identifying modulators of human IAP proteins (e.g. Abstract).

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One of the IAP polypeptides disclosed in the '912 patent (SEQ ID NO: 8) is ~99% identical to the amino acid sequence of c-IAP1 (SEQ ID NO: 2) disclosed by the instant application. This human IAP protein comprises first and second domains identical to SEQ ID NO: 5 and SEQ ID NO: 7, respectively (see the attached search reports). Thus, the issued patent teaches an isolated human cellular inhibitor of apoptosis protein comprising at least two of the recited domains.

The instant specification teaches that c-IAP1 and c-IAP2 mutants comprising the 3 BIR domains bind TRAF1 and TRAF2 (e.g. see pages 11-12). Given the great similarity between the two proteins (i.e. only four amino acid changes between SEQ ID NO: 2 of the instant specification and SEQ ID NO: 8 of the '912 patent) and given that there is only a single amino acid difference between the two proteins within the 3<sup>rd</sup> BIR domain (i.e. cytosine for glycine at residue 308), one of skill in the art would necessarily expect the protein taught by Korneluk et al to bind the TRAF proteins.

Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

### ***Conclusion***

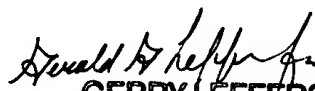
Claims 17-18 are rejected. Claims 19 and 22 are allowed. Claims 20 and 21 are withdrawn from consideration as being directed to nonelected inventions.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**GERRY LEFFERS** Gerald G Leffers Jr., PhD  
**PRIMARY EXAMINER** Primary Examiner  
Art Unit 1636

Ggl